UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,912	01/30/2004	Carl Ernest Alexander	4506-1025	2239

466 7590 05/26/2010
YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
05/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/766,912	ALEXANDER ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7,8,10,11,13,18,23-31 and 34* is/are pending in the application.

4a) Of the above claim(s) *10,11,18,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7,8,13,23-28,30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed February 2, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551 already of record) in view of Alexander (WO 2002/026078, English Equivalent 2004/0091431 already of record) and Grossmith (GB 750,126 already of record). The rejection is maintained and further applied to claim 34.

Applicant's Arguments

Applicant argues the combination of references do not teach or suggest a semi-solid composition wherein a gelling agent having a concentration such that a gel

framework of the gelling agent breaks apart and releases the active ingredient upon forcible disruption by a person. On the contrary, SCHMIDT teaches a water-soluble or water-swellable film-forming agent that is dissolved or dispersed in the mouth to distribute its substances and makes no teaching or suggestion of a breaking, or any quality of its thin film suggesting ability or a tendency to break apart in response to forcible disruption such as in an oral or dental procedure. ALEXANDER fails to teach a homogenous and non-encapsulated single-dose gel bead. Even if one of skill had motivation to modify SHMIDT to have a bead shape as taught by ALEXANDER, the result would fail to produce the composition that breaks apart as recited by the amended claims. GROSSMITH makes no teaching or suggestion of a composition suitable for use as a single-dose, semi-solid bead, as recited in the instant claims. It only teaches soft liquid like compositions with various viscosities. GROSSMITH expressly teaches away from any composition of agar-agar with solid or semi-solid properties. The combination as proposed by the Official Action would yield a semi-liquid that is, not semi-solid) jelly, formed into a bead- shape, which would be rendered into liquid form as a result of exposure to heat (syneresis) and mixture with water (see page i, e.g., lines 46-47 and 65-69). No motivation existed for one of skill at the time of invention to have modified SCHMIDT as proposed, at least because the thin film of SCHMIDT invention would fail to function satisfactorily if formed into a bead shape, either spherical or semi-spherical.

A bead shape will interfere with the dissolution of the composition because a bead shape so significantly reduces the amount of surface area compared to a thin foil

having the same volume and thus inhibits the composition from developing its full activity.

The combination as proposed to replace the composition of ALEXANDER with the composition of SCHMIDT formed as a bead would eliminate the advantages of ALEXANDER's shell and re-introduce the problems of poor shelf-life due to unintentional moisture exposure and spoilage through bacterial contamination.

GROSSMITH expressly teaches against a composition of agar in any kind of solid form, a solid or semi-solid composition that breaks apart being unsatisfactory to GROSSMITH's intended purpose. It is respectfully submitted that the jellies taught by GROSSMITH in the form of creams, pastes, etc. render SCHMIDT unsatisfactory for its intended purpose.

Examiner's Response

It is asserted that the compositions of Schmidt are dissolved or dispersed. Dispersed also encompasses to break apart. Thus this would encompass the instant claims' recitation of "break apart in response to forcible disruption", especially with the movements of the toothbrush. Although, Alexander teaches a capsule type toothpaste bead, it is used for its disclosure of different shapes suitable for children. Schmidt suggests making the compositions attractive to children and therefore one of ordinary skill in the art would recognize that modifying the shapes of Schmidt with the shapes of Alexander would be attractive to children. Schmidt also suggests the use of thickening agents other than those disclosed by the reference. Grossmith discloses thickening

agents that make gels with good texture and strength. It also teaches the components may be used as thickeners/and or gelling agents for toothpastes, and Schmidt discloses using thickeners and gelling agents in its films. Thus it would have been obvious to use these thickeners for their suitability and their advantageous properties. Further the reference teaches that these polymers have temperature stability, which would overcome problems with storing the compositions of Schmitt. It would be in the relative skill one of ordinary skill in the art to use these thickeners and reasonable for one of ordinary skill in the art to conclude that when dried the resulting gels would become films like those of Schmidt. Further, Grossmith discloses stronger gels may be made using less water (page 3, col. 1, lines 4-10). Therefore it is concluded that strong films may be made when dried because less water is present.

In regard to the Grossmith teaching away from agar agar compositions, the instant claims use the language "comprising of" which does not limit the compositions to only agar or carrageenan. Thus other thickeners in combination with agar are also encompassed by the instant claims. It is also noted that the instant specification teaches mixtures of agar and carrageenan, as well as mixtures including gelatin, and thus it is concluded that these combinations comprising agar are within the scope of the instant claims.

In regard to the shape, Schmidt discloses the compositions are dispersed by saliva or mechanical means such as a toothbrush. When placing a bead within the mouth, in order to convert the bead into toothpaste, it would have been obvious to have used the teeth as another mechanical means to disrupt or disperse the bead within the

user's mouth. Alexander suggests this in regard to the encapsulated bead disclosed by the reference (paragraph 058).

In regard to the instability, because the thickeners are water swellable, it would have been obvious to place the beads in blister packs to keep them from being exposed to moisture. The storing of beads in blister packs is also suggested by Alexander and therefore would have been obvious to one of ordinary skill in the art. This would further eliminate cross contamination.

In regard to claim 34, Grossmith also discloses carrageenan.

Response to Declarations

Declaration by Carl Ernest Alexander

Declarant asserts the inherent "brittle gel" property of agar causes the active ingredients of the dentifrice to be rapidly released from the bead at the commencement of the tooth cleaning procedure, at the end of a long shelf life.

Declarant notes that no other patent making use of the fragmentable nature of agar to quickly release active ingredients while providing a stable, temperature tolerant storage means was known or has since been discovered. The cited patents, Grossmith GB 750,126 and Schmidt US 5,354,551 were not considered during developments. Grossmith did not set out to provide a single-dose personal care preparation and teaches away from the instant invention. Grossmith would probably lead to a chewy composition that does not use a brush. Grossmith only discloses using the compositions of the reference as "stabilizers for toothpaste" and does not mention toothpaste

anywhere else. Further there is not advantage of modifying Alexander (2002) with Grossmith.

It is further asserted that the idea of a thin film that must dissolve before use does not appear to be consistent with our objective of provide an effective, quickly available, single-dose dentifrice without a capsule. The films of Schmidt would dissolve in mouth and tend to be swallowed immediately. Schmidt would not provide for varying shapes and a composition that is attractive to children has to simulate or improve on ordinary toothpaste as far as possible. Declarant further asserts the finding of Mr. Silcock (will be discussed below) call the compositions of Schmidt "gluggy". If the compositions were formed into beads, it would take much longer to dissolve. Further the compositions of the instant claims are preferred over those of other toothpastes because they do not have tackifiers such as carboxymethyl cellulose.

Examiner's Response

The Declaration is insufficient to overcome the rejection. Although Applicant may have not been aware of the teachings of Grossmith and Schmidt, these teachings were available and were known to those of ordinary skill in the art. It is submitted that Schmidt discloses that the compositions may be dissolved or dispersed. Dispersed encompasses break apart. Further one of ordinary skill in the film art would be able to make the films of Schmidt. This is evident by the second Declaration by Mr. Silcock, which will be addressed below. Grossmith discloses using the disclosed compositions comprising a combination of the thickening agents as components in toothpaste and

thus, suggests their suitability for use as a thickening agent in toothpaste, which are agents used in Schmidt. Schmidt discloses thickening agents used in toothpaste may be used in the disclosed compositions. Grossmith also discloses the compositions are stable at different temperature (page 3, col. 2, lines 20-25). Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Thus, it would have been obvious to one of ordinary skill in the art to use the thickening agents of Grossmith not only for their suitability but also because of their stability at different temperatures. Thus it does not appear Grossmith teaches away from Schmidt. This is further supported by the Declaration of Mr. Silcock on page 11 of 13, lines 17-23. Furthermore the term "gluggy" encompasses "pasty" and thus it would appear that a composition that was pasty would not be readily dissolvable and thus would not be swallowed right away, giving the actives time to be releases and used for brushing the teeth. It would also appear that if the compositions were beads, one would be motivated to crush them with the teeth. This is supported by the disclosure of Alexander (2002), and therefore the compositions would be dispersed in the oral cavity.

Declaration by Patrick Joseph Silcock

Declarant asserts there is no suggestion that agar or carrageenan alone is useful. The inability of compositions comprising only agar to be rubbed in would be undesirable for toothpaste.

The Declaration discloses Examples relating to the compositions of Schmidt and those relating to the compositions of the instant invention. The components differ from those used by the reference insofar as Amylogum is replace by Elastigel, which Declarant asserts is equivalent to Amylogum.

Declarant's results show the Schmidt formulations, film 1 and film 2A resulted in strong films. Film 2 did not form a good film due to the high water content, as mentioned earlier. As the humidity increased the films became more elastic and sticky.
Film 1 did not become toothpaste-like and could not be used as toothpaste. It poorly adhered to a toothbrush and when placed in the mouth it absorbed moisture, forming a viscous, slimy, cohesive (elastic) mass as it dissolved. Forming a bead accentuated the swelling and viscous, slimy, cohesive mouth feel and did not improve the ability to be used as a toothpaste with a toothbrush.

Film 2A was powdery in appearance and peeled best from the backing when warm. Adherence to a dry toothbrush was poor (fell off moving from brush to mouth). Adhesion to a wet toothbrush was acceptable however the film "melted" into the toothbrush bristles. In the mouth if taken dry the film formed a viscous, slimy, cohesive (elastic) mass as it dissolved, as per film 1 and if taken on a pre-wetted brush the film dissolved too quick to form a useful toothpaste.

On evaluation of the solid dosages of Alexander et al. (2004), the individual portions could be easily removed from the blister and placed on the toothbrush. On brushing using a dry or wet brush the solid dosage form rapidly dispersed to form a paste that resembled traditional toothpaste.

The films of Schmidt resulted in elastic, cohesive films that swelled and dissolved rather than deforming and dispersing to form toothpaste. Once the film hydrated it dissolved leaving no material on the toothbrush to clean the teeth. In addition, the films were sensitive to the environmental humidity. In contrast to the films of Schmidt the solid dosage of Alexander et al. (2004) was able to rapidly convert to toothpaste rather than dissolve. I would consider the toothpaste suitable for routine use. These experiments confirm that though the formulations appear similar the functionality and utility are very different.

Declarant further asserts, films of the combined references of Schmidt and Alexander are not advantageous because the film composition would still be exposed to environmental conditions such as humidity and contamination. Films of Schmidt in the context of Alexander (2002) and Grossmith would not result in an improved dental hygiene product and teach away from Alexander et al (2004).

Examiner's Response

The instant claims use open language and therefore encompass not only agar or carrageenan but also combinations of thickening agents. The instant specification further supports this combination and therefore the combination is within the scope of the instant claims.

In regard to the examples, the rejection is based on the modification of Schmidt with the thickening agents of Grossmith, yet there does not appear to be an Example in the declaration that shows the affect of using a combination of agar and another

thickening agent to make the compositions of Schmidt. The results show that the beads of Schmidt are sensitive to humidity. This would appear to be expected because they are made with materials that are water soluble. One of skill in the art would realize in order to preserve the compositions that it would be necessary to keep them sealed in a package such as a blister pack, which Alexander discloses may be used to package toothpaste beads. This would protect the beads from humidity and the mixture of thickeners from Grossmith would make them temperature stable. In regards to the texture of the beads made by Declarant, it would appear that when the compositions are formulated into a bead they would be crushed in order to advance brushing in order for the actives such as the surfactant and polishing agents to be released. This is also suggested by Alexander (2002). In regard to film 2A, it would appear that when melted on the toothbrush that the compositions would remain on the bristles because it was reported by Declarant that the composition was viscous, thus it is not certain how the film could have dissolved too quickly leaving nothing on the toothbrush as asserted by Declarant. It is not disclosed if a bead was made from the films of 2A and Declarant does not comment about what would occur if theses beads were stored in blister packs. It is also not disclosed how long the bead was left on the brush until being inserted into the mouth or what is encompassed by "too quickly" and therefore it cannot be independently concluded if the bead dissolved too quickly to be a useful tooth paste. Further, when the bead of film 1 did dissolve, it would appear that the surfactants and polishing agents mixed with saliva would still be present and Declarant has not mentioned what becomes of the agents that have been released from the bead.

In regard to the Example of Alexander 2004, it is not disclosed whether the beads of the art and the instant beads were made in the same dimensions. It would appear that if they were, they would sit on the toothbrush in the same manner. Further it does not appear to be disclosed why the beads of Alexander would sit on the brush, especially a dry brush better than those of the prior art. It is also not described what occurs when the bead of the instant claims is disrupted and how this makes a suitable toothpaste. It would be reasonable to conclude that pieces of agar are left in the mouth. Further, if this was not the case and the agar dissolved, it would seem that this would be similar to what occurs in the Schmidt films, where the thickeners dissolve and leave behind the actives that are released.

In regard to the Declarant's assertions in regard to Alexander et al., the reference was used for its disclosure of different shapes that would be attractive to children such as beads, not for it actual formulation of a bead. One of ordinary skill in the art would use this disclosure to make beads and shapes out of the films of Schmidt because Schmidt suggests making shapes that are attractive to children with the compositions disclosed. In regard to modifying the teachings of Schmidt and Alexander (2002) with Grossmith, Declarant has asserted that the mixture of agar with other polymers such as carrageenan would produce similar films to that of Schmidt, thus it would appear that one of ordinary skill in the art would use these thickeners to modify the teachings of Schmidt.

It does appear that the texture or structure of the beads made from only agar are different from those taught by the combined references of Schmidt, Alexander and

Grossmith, but these findings are not commensurate in scope with the instant claims. The claims use open language and thus the compositions would not only encompass agar but other gelling agent in combination with agar. The claims also recite personal care compositions, which would include skin care compositions, and oral care products other than toothpaste. Further the declaration fails to show a comparison between a bead/film with a mixture of agar and another gelling agent as disclosed by Grossmith and the beads of the instant invention. Declarant asserts the type of film or bead that would be formed if the gelling agents of Grossmith were used in place of those disclosed by Schmidt would not make suitable toothpastes yet provides not evidence to support this assertion.

Obvious-Type Double Patenting

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of copending Application No. 12/067817. The rejection is further applied to new claim 34.

This rejection is maintained pending appropriate action by applicant.

Claims 1, 3, 4, 7, 8, 13, 23-28, 30 and 34 are rejected.

Claims 10, 11, 18, 29 and 31 are withdrawn.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612